

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

1. (Currently Amended) A sustained release solid formulation characterized by comprising protein drug, sulfated polysaccharide, and hydrophobic material, wherein material selected from fatty acid, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof, wherein the pH of a mixture of the protein and sulfated polysaccharide is lower than the isoelectric point of the protein, and the mixture of protein and sulfated polysaccharide are is encapsulated with within a matrix of the hydrophobic material.

2. (Currently Amended) The formulation of claim 1 wherein said sulfated polysaccharide is selected from the group of dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

3. (Cancelled)

4. (Original) The formulation of claim 1 wherein said sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

5. (Currently Amended) A sustained release solid formulation comprising the The formulation of claim 1 wherein the composition further comprises and protein stabilizers.

6. (Currently Amended) The formulation of claim 5 wherein said protein stabilizer is selected from the group of sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran, polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose, hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

7. (Currently Amended) A process to prepare a sustained release solid protein drug characterized by comprising a step to prepare preparing a mixture of proteins and sulfated polysaccharides, a step to suspend suspending the mixture obtained in a non-aqueous solution containing hydrophobic materials, materials selected from fatty acid, pamoic acid, monoacyl glycerols, sorbitan fatty acid esters, diacyl glycerols, triglycerides, phospholipids, sphingosines, sphingolipids, waxes, and salts or derivatives thereof, and a step to remove removing a solvent from the suspension to obtain a solid protein drug, wherein the pH of the mixture of proteins and sulfated polysaccharides is lower than the isoelectric point of the protein.

8. (Original) The process of claim 7 wherein said sulfated polysaccharide is selected from dextran sulfate, chondroitin sulfate, dermatan sulfate, heparin, heparan sulfate, and keratan sulfate.

9. (Cancelled)

10. (Original) The process of claim 7 wherein said sulfated polysaccharide is present in an amount of from 0.01 to 95% weight of the formulation.

11. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a solid microparticulate form.

12. (Original) The process of claim 11 wherein said solid microparticulate is prepared by drying the liquid mixture of protein and sulfated polysaccharide.

13. (Original) The process of claim 12 wherein said solid microparticulate is obtained by spray drying, freeze drying, spray freeze drying, and drying using supercritical fluid.

14. (Original) The process of claim 7 wherein the mixture of protein and sulfated polysaccharide is a liquid state.

15. (Cancelled)

16. (Currently Amended) The process of claim 7 wherein the process further comprises a step to add adding protein stabilizers.

17. (Currently Amended) The process of claim 16 wherein said protein stabilizer is selected from the group of sucrose, trehalose, maltose, mannitol, lactose, mannose, polyol, dextran, polyethyleneglycol, cyclodextrin, polyvinylalcohol, hydroxypropylmethylcellulose,

hydroxyethylcellulose, polyethyleneimine, polyvinylpyrrolidone, gelatin, collagen, albumin, surfactants, amino acids, inorganic salts, and mixtures thereof.

18. (Cancelled)

19. (Cancelled)